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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John Walker

9643

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EXAMINER

KIM, YUNSOO

ART UNIT

PAPER NUMBER

1644

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/857,797	Applicant(s) WALKER, JOHN	
	Examiner YUNSOO KIM	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/10 has been entered.
2. Claims 23-42 are pending and are under consideration.
3. Applicant's request for an interview prior to issuance of an office action filed on 12/17/10 has been acknowledged. However, the attempts to contact the undersigned attorney, Victor Donahue, on 2/2/11 and 2/3/11 to schedule the interview have not been successful. The undersigned number does not allow leaving voice messages.
4. The following rejection remains.
5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. Claims 23-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2,228,262A, of record, in view of WO99/27959, of record, and U.S. Pat. No. 4,900,549, of record, for the reasons set forth in the office action mailed 3/17/10.

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The '262 application teaches a composition comprising a GnRH- diphtheria toxoid (DT) conjugate and an alum (aluminum hydroxide) as an adjuvant (claims 1-10). The '262 publication further teaches that GnRH is also known as LHRH (p. 1, line 21) and the composition comprising 20ug of GnRH-DT (p. 18).

The currently amended claims 23-31 and 40-42 are included in this rejection. Note that the claimed saponin is not a saponin compound but saponin component and the saponin component is an immunostimulating complex (note claim 27). As is evidenced by claims 27, 30 and 31, the immunostimulating complex allows other ingredients in the complex. As the dependent claim 27 allows addition of other ingredients, the dependent claim 23 allows other ingredients in spite of recitation of "consisting of".

Moreover, note that claim 40-42 do not exclude "immunoadjuvant oil" in recitation of "comprising".

The disclosure of the '262 publication differs from the instant claimed invention in that it does not teach the use of ionic polysaccharide (e.g. DEAE-dextran) and an immuno-stimulating complex comprising a saponin and a cholesterol as in claims 23-42.

The '959 publication teaches an adjuvant composition comprising a saponin and a DEAE-dextran (claims 1-22). The '959 publication teaches that the saponin is QuilA (Example 3), that said adjuvant composition improves adjuvanticity (p. 2-3) than alum and induces long lasting antibody responses and is suitable for use with various antigens (p. 7-8).

Moreover, the '959 publication teaches that a common vaccine formulation comprises an antigen and aluminum hydroxide gel (alum) as an adjuvant and there are some problems associated with this adjuvant. The alum adjuvant often fails to induce sufficient immune response and it is not acceptable for routine use because of inflammation, granulomas, ulceration and other lesions at the injection sites (p. 1-2, overlapping paragraph). The referenced adjuvant composition

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comprises saponin and DEAE-dextran enhances the effectiveness of an antigenic substance (p. 2).

Given that the mass ratio between the DEAE-dextran and saponin of about 125 is recited in claim 29, claim 29 is included in this rejection because the '959 publication discloses the upper range of saponin is 1mg/ml and the upper range of the DEAE-dextran is 150mg/ml (claims 14 and 16) which results in about 150 mass ratio. In light of this, claims 30, 31 and 35 reciting particular concentration of 10-100mg of DEAE-dextran and 80-800ug of saponin as the referenced concentrations of the saponin and DEAE-dextran are encompassed (claims 14 and 16).

The '549 patent teaches the addition of a cholesterol in adjuvant compositions comprising Quil-A and that the cholesterol stabilizes antigenic species and improves immunogenic activity (col. 1, lines 45- 68, col. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ and/or substitute alum adjuvant as taught by the '262 publication with an adjuvant composition comprising DEAE-dextran, saponin and cholesterol as taught by the '959 publication and the '549 patent.

One of ordinary skill in the art would have been motivated to do so because the adjuvant composition taught by the '959 publication and the '549 patent improves overall immune response by providing an improved adjuvant activity. The Quil-A and DEAE-dextran adjuvant taught by the '959 publication enhances the effectiveness of an antigenic species in stimulating an immune responses to a much greater extent than alum adjuvant and the cholesterol stabilizes antigenic species and improves immunogenic activity.

From the teachings of references, it would have been obvious to one of ordinary skill in art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie

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obvious to one of ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 12/17/10/ have been fully considered but they were not persuasive.

Applicant has asserted that the combination of the references is based on the hindsight and there is no motivation to combine the reference. Applicant has further asserted that the '959 publication invariably contain immunoadjuvant oil while the claimed invention does not allow addition of immunoadjuvant oil. Moreover, Applicant has asserted that the rejection is made over the teachings that are absent from the reference of record (p. 8 of response filed on 12/17/10). Applicant has further asserted that the '959 publication discloses DEAE dextran and saponin in the presence of mineral oil but does not mention use of cholesterol.

Upon further consideration of the '959 publication, the term "synergically", which Applicant has asserted not apparent, has been deleted from the body of the rejection. Note that the term "synergically" has been removed. However, the '959 publication is still valid for prior art. It is known in the art that the adjuvant comprising DEAE-dextran and saponin improves antibody titer than the alum (p. 2-3 overlapping). The '959 publication states:

"...it also discloses the use of a novel adjuvant comprising DEAE dextran and saponin or aluminum hydroxide and notes an improved antibody titer when the two component immunoadjuvants used (p. 2-3 overlapping paragraph)."

Therefore, even though synergy is not present, the adjuvant comprising DEAE-dextran and saponin is still a better adjuvant over alum alone. The '959 publication clearly provides motivation to substitute alum adjuvant with adjuvant comprising DEAE-dextran and saponin.

Further, motivation to add cholesterol is from the '549 patent. Note that the '549 patent teaches that the addition of cholesterol improves stability of the antigenic species and improve immunogenic activity. The '959 publication does not exclude cholesterol in the composition comprising a saponin. Rather, the '959 publication discloses that the field of adjuvant art

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recognizes the use of cholesterol with Quil A saponin (p.2, lines 14-16) and the '549 patent specifically teaches the use of cholesterol in the presence of Quil-A to stabilize antigenic species and improves immunogenic activities.

One cannot show nonobviousness by attacking references individually where the rejection is based on that the combination of the references. See MPEP 2145. Therefore, the combination of the references is obvious.

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
February 7, 2011

/Yunsoo Kim/

Examiner, Art Unit 1644